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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,868

08/26/2008

Alex Haahr Gouliaev

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EXAMINER

WOOLWINE, SAMUEL C

ART UNIT

PAPER NUMBER

1637

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,868	<b>Applicant(s)</b> GOULIAEV ET AL.	
	<b>Examiner</b> SAMUEL WOOLWINE	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 46-48, 52, 53, 81, 82, 85 and 174-178 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 46-48, 52, 53, 81, 82, 85 and 174-178 is/are rejected.
- 7) ☒ Claim(s) 82, 85 and 174 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/29/2008</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Status***

By Applicant's preliminary amendment filed 08/26/2008, claims 1-10, 12, 46-48, 52, 53, 81, 82, 85 and 174-178 are pending. Claims 1, 9, 85 and 174 are independent.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Objections***

Claims 82, 85 and 174 are objected to because of the following informalities:

Claim 82: the word "entity" is misspelled.

Claim 85: there is an inappropriately placed period in the middle of the claim (after the "separating" step).

Claim 174: the term "identifier polynucleotide" has been juxtaposed to "polynucleotide identifier" (in the "reacting" step).

Appropriate correction is required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 12, 46-48, 52, 53, 81, 82, 85 and 174-178 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 9, 10, 12-15, 22-24, 26, 29, 38, 39, 57, 68, 71, 74, 78-80, 84, 91, 121-124, 126, 130 and 131 of copending Application No. 10/549,619. Although the conflicting claims are not identical, they are not patentably distinct from each other. While the claims differ somewhat in scope and terminology, they define essentially the same invention.

For example, claim 1 of the '619 application uses the term "template" rather than "connector oligonucleotide" as recited in the instant claims, but it is readily apparent that these terms are indistinguishable.

Claim 1 of the '619 application also uses the term "anti-codon" rather than the term "identifier oligonucleotide" as recited in the instant claims. An "anti-codon" is described in the '619 application as follows (paragraph [0062]): "Each codon or anti-codon or building block oligonucleotide preferably comprises or consists of a sequence of nucleotides." Therefore, the terms "anti-codon" and "oligonucleotide" are indistinguishable; each is nothing more than a sequence of nucleotides.

Claim 1 of the '619 application recites "covalently linking" the anti-codons of building blocks hybridized to the template, whereas instant claim 1 recites "ligating" the identifier oligonucleotides of building blocks hybridized to the "connector oligonucleotide". However, as the term "ligating" as used in the '619 application clearly includes "chemical ligation", the term does not distinguish over "covalently linking" as recited in the instant claims.

Claim 1 of the '619 application recites providing "at least one template", whereas instant claim 1 recites providing "one or more connector oligonucleotides". Therefore, claim 1 of the '619 application meets the limitation "one or more" of instant claim 1, though there is a difference in scope.

Claim 1 of the '619 application and instant claim 1 recite hybridizing building blocks to the template/connector oligonucleotide, ligating the oligonucleotides (or anti-codons) to form an identifier polynucleotide, and separating the identifier polynucleotide from the template/connector oligonucleotide prior to reacting the chemical entities of the identifier polynucleotide to produce the bifunctional complex. See for example figure 8 of the '619 application.

Regarding instant claims 2 and 3, claim 10 of the '619 application discloses that at least one of the anti-codons (indistinguishable from the instantly claimed "identifier oligonucleotides") is covalently linked to a solid support. See for example figure 11A and B of the '619 application.

Regarding instant claim 4, claim 121 of the '619 application discloses that the covalently linked anti-codons (i.e. the "identifier polynucleotide" as recited in the instant

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claims) can be separated from the template (i.e. the "connector oligonucleotide" as recited in the instant claims), the template may be removed from the compartment by transferring it to a second compartment, followed by the reaction of the chemical entities associated with the identifier polynucleotide.

Regarding instant claim 5, claim 23 of the '619 application discloses further reaction with a further building block to obtain a second bifunctional complex.

Similar parallels occur between the remaining claims of the instant application and the '619 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

As set forth in MPEP 804(I)(B)(1):

*If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.*

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

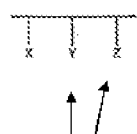
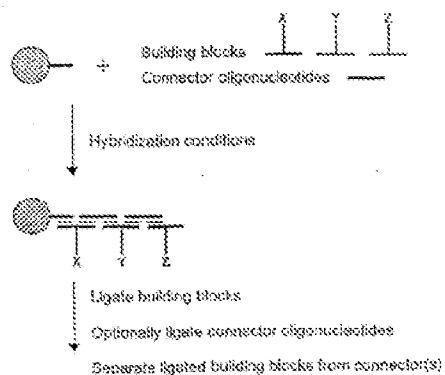
Claims 3-5, 7, 9, 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 5 and 12, the phrase "for example" (or "e.g.") renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 3 recites the limitation "hybridising said immobilized building block oligonucleotide...". There is insufficient antecedent basis for this limitation in the claim, as the claim previously recites "immobilizing at least one building block to a solid support" (saying nothing about an oligonucleotide). Claim 1, from which claim 3 depends, only requires that "at least some" building blocks comprise an identifier oligonucleotide, hence the term "building block" does not necessarily imply an oligonucleotide as a component. Applicant is advised to amend "immobilizing at least one building block to a solid support" to "immobilizing at least one building block comprising an identifier oligonucleotide to a solid support".

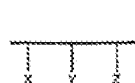
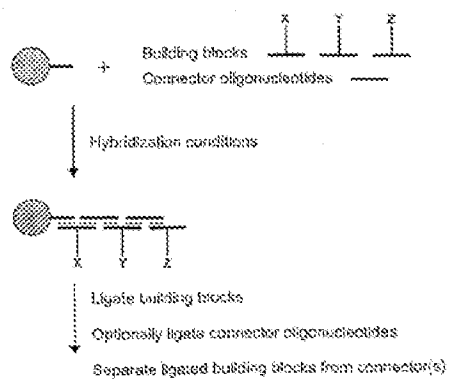
Claim 3 is also vague and indefinite because of the limitation "reacting one or more chemical entities associated with different, ligated and separated building block oligonucleotides". It cannot be determined whether "different" used here means that the chemical entities are part of different oligonucleotides, which have been ligated together, or whether the chemical entities are part of different ligated oligonucleotides. In other words, this:

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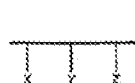
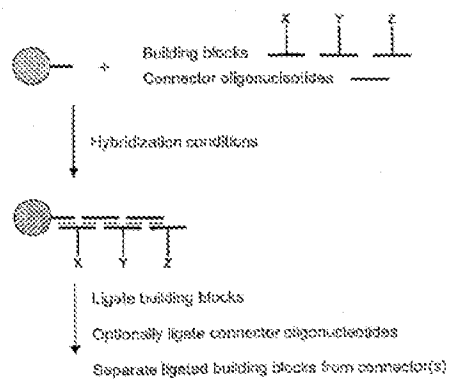


Reaction occurs between x, y and/or z

or this:



1



2

Reaction occurs between ( $x^1$ ,  $y^1$  or  $z^1$ ) and ( $x^2$ ,  $y^2$  or  $z^2$ )



In addition, claim 3 is vague and indefinite based on the limitation "...having participated in the synthesis of the molecule, or molecule precursor...". The term "molecule precursor" lacks antecedent basis in the claim. Claim 1, from which claim 3 depends, recites "bifunctional complexes each comprising a) a molecule resulting from the reaction of a plurality of chemical entities..."; claim 1 says nothing about a "molecule precursor". Furthermore, what is the difference between a molecule and a molecule precursor? Applicant is advised to provide antecedent basis for "molecule precursor" or, alternatively, adopt language such as "first molecule", "second molecule", etc, where the "first molecule" could be further reacted with additional chemical entities to produce the "second molecule" (hence acting as a "precursor"). As claims 4 and 5 depend from claim 3, they are rejected for the same reason.

Claim 7 recites the limitation "is released from the solid support to which it is immobilised". There is insufficient antecedent basis for this limitation in the claim, since claim 1, from which claim 7 depends, says nothing about any solid support.

Claim 9 recites "all chemical entities to be reacted are linked to the same identifier nucleotide" (last two lines). It is unclear what "identifier nucleotide" refers to. Does it refer to the previously recited "identifier oligonucleotide" or the previously recited "identifier polynucleotide"? As claim 10 depends from claim 9, it is rejected for the same reason.

Claim 178 recites "...by carrying out the steps of the method of the invention using...". It is not clear exactly what steps are being referred to here. Applicant is

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advised to either recite the explicit steps or refer back to the steps of whatever claim or claims is intended.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL WOOLWINE whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel Woolwine/  
Examiner, Art Unit 1637